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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,615	07/08/2003	Clemens Hendricus, M. Kocken	2183-6041US	8276
24247	7590	10/02/2006		
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			EXAMINER GUIDRY, GUY L	
			ART UNIT	PAPER NUMBER

1636

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/615,615	Applicant(s) KOCKEN ET AL.	
	Examiner Guy Guidry, Ph.D.	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 8-10, 12, 15-23, 25-30, 32, 33, 35-37, 39, 42 and 43 is/are pending in the application.
- 4a) Of the above claim(s) 12, 15-23, 25, 26, 32, 33, 35-37, 39, 42 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 8-10 and 27-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/10/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 July 2006 has been entered. Claims 1-4, 6, 8-10, 12, 15-23, 25-30, 32, 33, 35-37, 39, 42 and 43 are pending in this application. Claims 1-4, 6, 8-10 and 27-30 are under consideration in this action. All objections/rejections not repeated herein are hereby withdrawn. Where applicable a response to Applicant's arguments is set forth immediately following the body of the any objection/rejection set forth herein. This action is Non-Final.

Claim Objections

Claims 1 and 27 are objected to because of the following informalities: the claims refer to "consisting of parts spanning from amino acid residue 25-442, 97-318, 97-442 and 97-545...as depicted in FIG. 1" where the number of residues in FIG. 1 can only refer to nucleic acid nucleotides, not amino acid residues. Removing the term "amino acid" from the claims would be remedial in this instance. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6, 8-10 and 27-30 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Response to amendments

This rejection is directed to the amendment to claims 1 and 27, and therefore all dependent claims, wherein the encoding nucleic acid "consists" of a sequence as depicted in FIG. 1. The limitation "consists of" a specific sequence is not contemplated in the specification and was not previously considered in any previous claim, therefore the amendment represent inadmissible NEW MATTER. Applicant is directed to either explain why the matter should be entered or to amend the claims so that the new matter is deleted.

Claims 1-4, 6, 8-10 and 27-30 are rejected for claims to portions of the sequence of FIG. 1 and all sequence with at least 90% homology to said portions. The number of possible nucleotide sequences that are of a given % identity relative to a reference sequence, where all differences between the possible sequences and the reference sequence are substitutions, can be calculated by the following formula:

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$$N = XL + X^2L(L-1)/2! + X^3L(L-1)(L-2)/3! + \dots + X^{n-1}L(L-1)(L-2)\dots(L-(n-2))/(n-1)! + X^nL(L-1)(L-2)\dots(L-(n-1))/n!$$

where N is the number of possible sequences, X is the number of different residues that can be substituted for a residue in the reference sequence, L is the length of the reference sequence, n is the maximum number of residues that can be substituted relative to the reference sequence at a given % identity. For a nucleotide sequence, X is 3 (alternate nucleotides); for an amino acid sequence, X is 19 (alternate amino acids). The first term gives the number with one substitution, the second with two substitutions and so on to the number with n substitutions. The last term can be simplified for calculation to: $X^n L! / n! (L-n-1) !$

Thus, for the shortest sequence cited, residues 97-318 of FIG. 1 containing 221 base pairs, with 3 alternate nucleotides and 22 (10% of 221 or 90 % identity) residues that can be substituted relative to the reference, the number of possible variants is

$3^{22} 221 ! / 21 ! (221-21-1) !$., represents an exceptionally a large number of potential sequences for which the disclosure is silent. Determining which sequences have the recited functionality of having antigenicity of *Plasmodium falciparum* apical membrane antigen-1 is well beyond the written description provided in the instant specification. Relevant characteristics which comprise the antigenicity of *Plasmodium falciparum* are not disclosed, beyond the providing of sequence information which comprises the entire apical membrane antigen-1.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 8-10 and 27-30 stand rejected under 35 U.S.C. 102(b) as being anticipated by Kocken (of record).

Response to amendments and arguments

Applicant argues that Kocken fails to teach expression of *P. falciparum* AMA-1 ectodomain or functional part thereof selected from the group consisting of parts spanning from residues 25-442, 97-318, 97-442 and 97-545. Applicant's arguments have been considered and they are not persuasive. The claims are given broadest possible interpretation. The Office interprets the claim limitations "nucleic acid encoding said ectodomain or functional part thereof selected from the group spanning..." to comprise the full ectodomain, thus Kocken teaches the full ectodomain and all parts thereof. Further, the limitation "wherein the encoding nucleic acid consists of a sequence that has 90 percent homology to **the corresponding sequence** as depicted in Fig. 1" is ill defined. It is not clear that "the corresponding sequence" is limited to those fragments that are recited in the claims. Furthermore, the 90% homology limitation allows for substantial insertions and deletions. Such sequences with insertion and/or deletions covered by the 90% homology limitation may be considered to be anticipated by the prior art.

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Therefore, claims 1-4, 6, 8-10 and 27-30 stand rejected as being anticipated by Kocken.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6, 8-10 and 27-30 rejected under 35 U.S.C. 103(a) as being unpatentable over Kocken (of record) and in further view of Withers-Martinez (of record).

Response to amendments and arguments

Applicant argues that Kocken fails to teach expression of *P. falciparum* AMA-1 ectodomain or functional part thereof selected from the group consisting of parts spanning from residues 25-442, 97-318, 97-442 and 97-545. Applicant also argues that Withers-Martinez fail to teach an AMA-1 ectodomain in natural conformation and that Withers-Martinez teaches expression in insect cells rather than yeast as in the instant claims. Applicant also argues that no motivation exists to combine the two references because independent claims 1 and 27 require the ectodomain exhibit specificity for mAB 4G2 but Applicant alleges, the protein collected by Withers-Martinez is not in its natural conformation.

Applicant's arguments have been considered and they are not persuasive. The claims are given broadest possible interpretation. The Office interprets the claim limitations "nucleic acid encoding said ectodomain or functional part thereof selected from the group spanning..." to comprise the full ectodomain, thus Kocken teaches the full ectodomain and all parts thereof. Further, the ectodomain described by Withers-Martinez is considered to contain, in at least a portion, AMA-1 ectodomain in native folded conformation, and further the protein collected from insect cells described by Withers-Martinez is correctly folded, making obvious the instant claims because a person of skill would have been motivated to *combine* the teachings of Kocken and Withers-Martinez to derive a properly folded AMA-1 ectodomain, some of which would have been derived from expression in yeast cells. The Office does not have the facilities for examining and comparing Applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2d 1922, 1923 (BPAI 1989). Therefore, claims 1-4, 6, 8-10 and 27-30 stand rejected as being unpatentable over Kocken and Withers-Martinez.

Conclusion

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No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Guy Guidry, Ph.D. whose telephone number is 571-272-7928. The examiner can normally be reached on Monday through Friday 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (<http://pair-direct.uspto.gov>) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the

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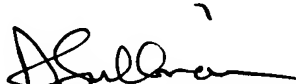
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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Guy Guidry, Ph.D.

Examiner

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DANIEL M. SULLIVAN
PATENT EXAMINER